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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,905	02/25/2002	Claude Saliou	J&J-2091	3183
27777	7590	06/29/2004	EXAMINER	
<b>PHILIP S. JOHNSON</b> JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				WITZ, JEAN C
		ART UNIT		PAPER NUMBER
		1651		

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/082,905	SALIOU ET AL.
Examiner	Art Unit	
Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 19 April 2004.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 16,17,21-29 and 31-40 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 16,17,21-29 and 31-40 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 19, 2004 has been entered.

### ***Response to Arguments***

Applicant's arguments filed April 19, 2004 have been fully considered but are deemed moot in view of the new grounds of rejection.

### ***Claim Objections***

2. Claims 21-25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 21-25 all recite the limitation "wherein the method is for the treatment of external aggressions of the skin." This limitation is already present in the claims from which they depend; therefore, these claims fail to further limit the claims from which they depend.

Claims 34 and 35 appear to have the term "of" missing after the term "result". Correction is required.

***Claim Rejections - 35 USC § 112***

3. Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 36-40 recite subject matter that is not described in the specification and therefore constitutes "new matter".

4. Claims 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes, bounds and scope of the term "promoting" is unclear as broadest reasonable interpretation of the term encompasses multiple meanings; Applicants have not presented any definition of this term in the specification and therefore it remains unclear as to what Applicants intend the term to encompass.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 16-17, 21-29, 35 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamura et al. (U.S. Patent 5,306,444).

The claims are drawn to the treatment of external aggressions to the skin, nails or hair wherein the aggressions result from environmental chemical contact and temperature comprising the topical application of a soy product having a trypsin inhibitory activity of at least about 15%.

Kitamura et al. disclose a composition applied to the skin to treat and ameliorate skin irritation caused by skin contaminants containing soybean trypsin inhibitor (STI). It is deemed that "contaminants" falls well within the broadest reasonable interpretation of the term "environmental chemical contact" and is therefore deemed inherent in the disclosure of the reference. Applicants' attention is directed to Table I-1, where Composition I-5 contains 0.1 % STI. Per Applicants' disclosure in Table 1 at page 22 of the specification, a 0.1% composition of STI had a thiol retention activity of 76.1. Therefore Composition I-5 is deemed to meet the limitations of claims 26-29. With regard to claim 35, it is deemed inherent that the irritation disclosed in the patent was caused by smoke, since smoke is a constant air contaminant, particularly in areas of high population density. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art method. See *In re*

Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and Ex parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) .

With regard to claims 36, 39 and 40, the disclosure of Kitamura, by its very definition as teachings of the prior art, explicitly teach directions for use of a composition as claimed to be used for the treatment of external aggressions of the skin as defined by the claim, thereby anticipating the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-17, 21-29, and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Kitamura et al. (5,306,444) combined with Hofmann (5,194,252).

The disclosure of Kitamura et al. is discussed *supra*.

Hofmann teaches that a soy product, specifically a soy protein hydrolysate acts on the skin to form smoothing films, helps to minimize roughness and wrinkles, forms a moisture retentive film, combats chapping and irritation caused by detergents, and protects the skin from environmental damage (including pollutants). Starting at col. 5, multiple aftershave lotions are disclosed as containing the soy protein hydrolysate.

Clearly, both STI and soybean products are known to be included in products used to treat the skin for the benefit of improvements to the skin and amelioration of damage to the skin. Therefore, it would have been obvious to one of ordinary skill in the art to use a conventional soy product such as a soybean powder or a soymilk powder to treat damage to the skin due to external aggressions such as environmental chemicals and temperature. Since the Hoffman product teaches that it combats chapping and irritation caused by detergents (whose action is often due to their dehydrating action and their removal of natural skin emollients – see Kitamura), it would have been obvious to use the same composition against chapping and irritation caused by either hot or cold temperatures with the reasonable expectation of a beneficial effect. Absent objective evidence to the contrary, it would be expected that the disclosed soy

products would have a beneficial effect on damaged skin regardless of the cause.

Given the disclosure of the importance of the many components of the soybean, one of ordinary skill in the art would have been motivated to produce a product that contained as many of these components, including soybean trypsin inhibitor, for their expected beneficial contribution to the damaged skin, thereby producing a product having the thiol retention characteristics as claimed. Absent objective evidence to the contrary, the soy products disclosed in the cited references, because they are expected to contain the STI active ingredient, are deemed to inherently contain the thiol retention activity claimed. Where Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103. *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). “[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency’ under 35 U.S.C. 102, on *prima facie* obviousness’ under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted].” The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

As the prior art indicates that a wide range of concentrations may be used which are within the range claimed, it is clear that optimization of the amount of the product to be administered is well within the skill of the practitioner.

With regard to claims 36-40, the disclosures of both Hoffman and Kitamura, by their very definition as teachings of the prior art, suggest directions for use of a composition as claimed to be used for the treatment of external aggressions of the skin. As stated above, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to direct use for other sources of skin damage, such as damage due to hot or cold temperatures.

Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamura et al. (5,306,444) combined with Hofmann (5,194,252) as applied to claims 16-17, 21-29, and 33-40 above, and further in view of JP 63227515.

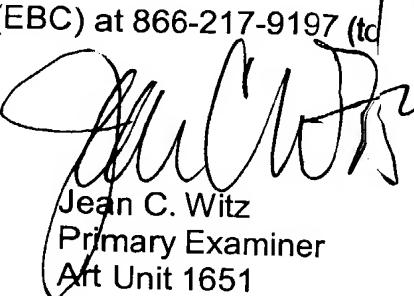
The treatment of the compositions with gamma radiation to reduce the microbiological load of the compositions is clearly a conventional choice of the practitioner as evidenced by the disclosure of JP 63227515 that teaches that cosmetics are conventionally sterilized by exposure to gamma radiation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926.

The fax phone number for the organization where this application or<sub>ng</sub> is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).



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